No. 96-1749

Supreme Court, U.S.
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In The

Supreme Court of the United States

October Term, 1996

ADA M. MARTIN and HAROLD L. MARTIN,

Petitioners,

vs.

TELECTRONICS PACING SYSTEMS, INC.; TPLC, INC. d/b/a Telectronics Pacing Systems; TELECTRONICS PTY LIMITED,

Respondents.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Sixth Circuit

RESPONDENTS' BRIEF IN OPPOSITION

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RULE 29.6 STATEMENT

Respondents Telectronics Pacing Systems, Inc., TPLC, Inc. d/b/a Telectronics Pacing Systems, and Telectronics PTY Limited, are related corporations that are each beneficially owned by Pacific Dunlop, Ltd. as the ultimate parent corporation. A list of all Pacific Dunlop, Ltd. subsidiaries is submitted as a Lodging Appendix.

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COUNTERSTATEMENT OF THE CASE

Respondents generally accept as accurate the Statement of the Case included in the Petition for Writ of Certiorari. Pursuant to Sup. Ct. R. 15.2, however, Respondents address the following perceived misstatement of fact included in Petitioners' brief.

This case involves the question of federal preemption under the Medical Device Amendments ("MDA") to the Food, Drug and Cosmetic Act. The underlying lawsuit is a product liability action in which Petitioners claim to have been injured by a medical device, known as the Telectronics Guardian 4210 Cardioverter/Defibrillator (the "Guardian System"), prescribed by a doctor to treat Petitioner Ada Martin's heart condition. Petitioners accurately describe the Guardian System as a device "which provides combined functions of a defibrillator with a cardioverter and a pacemaker." Pet. at 2. Petitioners concede that "[t]he Guardian 4210 System, *including all four component parts*, is a medical device currently subject to investigational testing pursuant to the Medical Device Amendments to the 1938 Food, Drug and Cosmetic Act." Pet. at 2-3 (emphasis added). Petitioners further concede that "the product *system* had secured 'investigational device exemption ["IDE"]' " under the MDA. *Id.* at 3 (emphasis added).

Notwithstanding these candid admissions, Petitioners contend that "two of the four components of the 4210 system . . . were used *in the system* under a Section 510(k) exemption and not through the IDE exemption." *Id.* (emphasis added). This contention is erroneous and must be rejected by this Court for several reasons.

First, Petitioners' statement reveals a fundamental misunderstanding of the statutory and regulatory provisions governing medical devices. Respondents readily acknowledge that, at different times and in different contexts, the Food and Drug Administration ("FDA") authorized for market distribution two discrete components of the Guardian System upon a finding of "substantial equivalence" under section 510(k) of the MDA. This is not to say, however, that the FDA's finding of "substantial equivalence" authorized Respondents to

use these components in an experimental or investigational context such as the one at issue here. *See, e.g., Oja v. Howmedica, Inc.*, 111 F.3d 782, 1997 U.S. App. LEXIS 7175 (10th Cir. 1997) (describing FDA authorization to conduct clinical investigation of a device "in an experimental context" that, in a different configuration, had been authorized for market distribution under section 510(k)).

By definition, an investigational device is one for which there is insufficient information for the FDA to make a determination as to its safety and effectiveness. *See generally* 21 U.S.C. § 360j(g); 21 C.F.R. § 812.1 *et seq.* (generally describing purpose of investigational device exemption). In other words, the proposed device is new. By contrast, a finding of substantial equivalence presupposes that the device "has the same intended use" and "the same technological characteristics" as a "predicate device" which is already on the market. *See* 21 C.F.R. § 807.100(b) (criteria for determining substantial equivalency). Where, as here, the device is part of a unique configuration comprised of several components which, taken together, form a completely new device, there is no "predicate device" with the same intended use and thus no basis for a finding of substantial equivalence. Accordingly, while some of the Guardian System's component parts may have been governed by section 510(k) regulations when used in other contexts, there is no doubt that they were governed by the investigational device exemption regulations in the only context relevant to these proceedings.

Second, Petitioners' statement is an impermissible re-argument of facts. At trial, Respondents argued that Petitioners' claims were preempted by federal regulations governing investigational devices. *Martin v. Telectronics Pacing Systems, Inc.*, 105 F.3d 1090, 1097 (6th Cir. 1997). In the alternative, Respondents noted that two components of the Guardian System had been separately reviewed by the FDA under federal regulations governing "substantially equivalent" devices and submitted that preemption would be appropriate under those regulations as well. *Id.* The trial court accepted as fact that the components were part of the investigational device at issue, and appropriately proceeded to analyze the preemption question in view of the investigational device regulations. *Id.* at 1098. Significantly,

Petitioners never challenged, and conceded at every turn, the factual premise underlying the trial court's analysis. *Id.* at 1097-1098. The appellate court declined Petitioners' invitation to re-examine facts which Petitioners had conceded at trial, *id.* at 1098, and this Court should similarly reject Petitioners' attempt to reargue or assert new and different facts on appeal.

Third, Petitioners' attempt to refashion its case on appeal should be recognized and rejected for what it is: an undisguised attempt to bootstrap onto this Court's recent decision in *Medtronic, Inc. v. Lohr*, 116 S. Ct. 2240 (1996). In *Lohr*, this Court concluded in a five-to-four plurality decision that the MDA did not preempt certain common law claims against the manufacturer of a "substantially equivalent" device. Obviously, Petitioners recognize that characterizing the investigational device at issue here as a "substantially equivalent" device would allow them to take advantage of the *Lohr* decision. Accordingly, Petitioners have devoted substantial time and effort to "reclassifying" the device at issue both during the appeal after remand and again in their petition for a writ of certiorari

Petitioners explain their failure to raise this issue prior to *Lohr* by stating that it was "impossible for attorneys as well as lower courts to anticipate what the United States Supreme Court will find relevant or important." Pet. at 9. This argument is disingenuous. At the time the preemption issue was presented to the trial court, and certainly by the time the issue was first argued on appeal, federal and state courts at both the trial and appellate levels had already begun to draw sharp distinctions between "substantially equivalent" devices and other medical devices for purposes of conducting a preemption analysis under the MDA. The distinction has always been important. Respondents recognized it and argued in the alternative. Petitioners did neither. Accordingly, notwithstanding Petitioners' lament that the appellate court "chose to assert the pre-*Lohr* arguments of counsel as the true facts of the case," it is beyond cavil that the *Lohr* decision did not and cannot alter the facts established and conceded by Petitioners below. The device at issue here is an investigational device, governed by the investigational device provisions of the MDA.

For all of the foregoing reasons, Respondents respectfully disagree with Petitioners' statement that federal statutes and regulations governing "substantially equivalent" devices are applicable to the Guardian System or to any of its component parts.

REASONS FOR DENYING THE WRIT

I. THIS DECISION BELOW DOES NOT CONFLICT WITH DECISIONS OF OTHER COURTS OF APPEAL AND INTERPRETS THE STATUTE, 21 U.S.C. § 360k(a) CONSISTENTLY WITH CONGRESSIONAL INTENT AS INTERPRETED BY THIS COURT IN *MEDTRONIC, INC. v. LOHR*, 116 S. Ct. 2240 (1996) [RESTATED].

Petitioners assert that their petition should be granted because the Sixth Circuit Court of Appeals "improperly interpreted and improperly applied" this Court's decision in *Medtronic, Inc. v. Lohr*. Pet. at 6. Petitioners also argue that a writ for certiorari should be granted because the Sixth Circuit's decision conflicts with decisions from other federal appellate courts. *Id.* Respondents address each argument in turn.

A. *Medtronic, Inc. v. Lohr*

In *Medtronic, Inc. v. Lohr*, this Court addressed for the first time the preemptive scope of the MDA. At the outset, the Court reiterated the well-established principle that " '[t]he purpose of Congress is the ultimate touchstone' in every pre-emption case," *Medtronic, Inc. v. Lohr*, 116 S. Ct. 2240, 2250 (1996) (quoting *Retail Clerks International Ass'n v. Schermerhorn*, 375 U.S. 96, 103 (1963)), and noted that "any understanding of the scope of a pre-emption statute must rest primarily on 'a fair understanding of congressional purpose.' " *Id.* (citing *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 530 n.27 (1992)). Of course, this understanding starts with "the language of the pre-emption statute and the 'statutory framework' surrounding it." *Id.* at 2251 (quoting *Gade v. National Solid Wastes Management Ass'n*, 505 U.S. 88, 111 (1992) (Kennedy, J., concurring)). However, the *Lohr* Court also observed that "the 'structure and purpose of the statute as a whole,'

as revealed not only in the text, but through the reviewing court's reasoned understanding of the way in which Congress intended the statute and its surrounding regulatory scheme to affect business, consumers and the law," is relevant to a principled preemption analysis. *Id.* (quoting *Gade*, 505 U.S. at 98).

1. The Language of the MDA

Turning to the first step in this analytical process, the Court looked to the express preemption clause of the MDA which provides, in pertinent part:

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement —
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a).

The Court acknowledged that the above-quoted language is sufficiently clear to reveal that Congress intended "the MDA to pre-empt at least some state law. . . ." *Lohr*, 116 S. Ct. at 2250. Five justices, however, found that the MDA's preemption language was too ambiguous to indicate exactly what state laws should be preempted and in what circumstances. *See id.* at 2255 ("the language of that section is not entirely clear") (Stevens, J.); *id.* at 2260 (describing the MDA's express preemption provision as "highly ambiguous") (Breyer, J., concurring in part and concurring in the judgment). Accordingly, the Court looked to "the structure and purpose of the statute as a whole" for guidance in assessing the MDA's intended preemptive scope.

2. The Structure and Purpose of the MDA

Congress enacted the MDA in response to rapid growth in the use of medical devices to treat a variety of diseases and conditions, coupled with growing concern "about the increasingly severe injuries that resulted from the failure of such devices." *Lohr*, 116 S. Ct. at 2246. Prior to that time, there was no meaningful oversight of the medical device industry at any level, and no process comparable to that provided for pharmaceuticals whereby manufacturers were required to demonstrate the safety and efficacy of their products before distributing them in the market. *See id.*

When it enacted the MDA, Congress intended to change this status quo. The goals of the legislation are set forth in the text of the statute and in its legislative history. Of primary importance was the desire of Congress to improve "the safety and effectiveness of devices intended for human use." *Lohr*, 116 S. Ct. at 2253 (citing 90 Stat. 539). A second clearly articulated goal was to "encourage . . . research and development" of new, potentially lifesaving or life-enhancing medical device technology. *Id.* at 2253 & n. 12; S. Rep. No. 33, 94th Cong. 2d Sess. 1, 2 (1975), *reprinted in* 1976 U.S.C.C.A.N. 1070, 1071.

To accomplish these goals, the MDA first requires the FDA to classify every medical device into one of three categories based on the risk they pose to the public. *See* 21 U.S.C. § 360c(a)(1); *Lohr*, 116 S. Ct. at 2246. Devices intended "for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health" or which present "a potential unreasonable risk of illness or injury," are designated as Class III. *Id.* § 360c(a)(1)(C). Congress required all Class III device manufacturers to prove to the FDA that their products were reasonably safe and effective before they could begin distribution in the market. *See* 21 U.S.C. §§ 360c(a)(1)(C), 360e. This *a priori* review and approval requirement, "known as the 'premarket approval,' or 'PMA' process, is a rigorous one." *Lohr*, 116 S. Ct. at 2246-47. To obtain PMA approval, "[m]anufacturers must submit detailed information regarding the safety and efficacy of their devices." *Id.* at 2247. The FDA reviews this

information, "spending an average of 1,200 hours on each submission." *Id.*

Congress realized, however, when it enacted the MDA, "that existing medical devices could not be withdrawn from the market while the FDA completed its PMA analysis for those devices." *Id.* In other words, Congress knew the FDA could not expose hundreds or thousands of existing medical devices to PMA scrutiny overnight, and at the same time, could not bring the medical device industry to a crashing halt pending full implementation of the MDA's substantive provisions.

The solution, embodied in the MDA, was to allow already existing devices "to remain on the market without FDA approval until such time as the FDA initiates and completes the requisite PMA." *Id.* (citing 21 U.S.C. § 360e(b)(1)(A); 21 C.F.R. § 814.1(c)(1)). In addition, to prevent manufacturers of these "grandfathered" devices from "monopolizing the market while new devices clear the PMA hurdle," Congress also permitted post-enactment devices to enter the market without FDA approval so long as they were "substantially equivalent" to their pre-enactment predecessors. *See id.; see also* 21 U.S.C. § 360e(b)(1)(B).

The device at issue in *Lohr* was just such a "substantially equivalent" device. The *Lohr* Court noted that the process for determining whether a device was substantially equivalent to a pre-enactment device "is by no means comparable to the PMA process," and that unlike PMA approval, a finding of substantial equivalence does not establish that the device is reasonably safe and effective. *See Lohr*, 116 S. Ct. at 2254; *see also* 21 C.F.R. § 807.97 (finding of substantial equivalence "does not in any way denote official approval of the device"). As the Court observed,

> [S]ubstantial equivalence determinations provide little protection to the public. These determinations simply compare a post-1976 device to a pre-1976 device to ascertain whether the later device is no more dangerous and no less

> effective than the earlier device. If the earlier device poses a severe risk or is ineffective, then the later device may also be risky or ineffective.

Lohr, 116 S. Ct. at 2254 (citation omitted).

3. Applying the MDA's Preemption Provision

Having thus reviewed the language, the structure and the purpose of the MDA, the *Lohr* Court turned its attention to determining whether the particular state laws in that case were preempted by the MDA. Both the plurality and dissenting opinions undertook a careful comparison of the state law claims and the federal regulations applicable to Lohr's "substantially equivalent" device. Ultimately, a plurality of the Court concluded that the applicable federal laws did not preempt the state common law claims at issue. The underlying rationale for this conclusion, however, is not entirely clear, and no single approach to determining the MDA's preemptive scope commanded a majority.

Without belaboring the areas of agreement and disagreement found in the plurality, concurring and dissenting opinions, Respondent submits that the following summary fairly characterizes the Court's position:

(a) All nine justices apparently agreed that common law claims can impose "requirements" under color of state law. *See, e.g., Lohr*, 116 S. Ct. at 2259 ("it will be rare indeed [but apparently not impossible] for a court hearing a common-law cause of action to issue a decree that has 'the effect of establishing a substantive requirement for a specific device.' ") (Stevens, J.); *id.* at 2260 ("insofar as the MDA pre-empts a state requirement embodied in a state statute, rule, regulation, or other administrative action, it would also pre-empt a similar requirement that takes the form of a standard of care or behavior imposed by a state-law tort action.") (Breyer, J., concurring in part and concurring in the judgment); *id.* at 2263 ("If § 360k's language is given its ordinary meaning, it clearly pre-empts any state common-law action that would impose a requirement different from, or in addition to, that applicable under the [MDA].") (O'Connor, J., concurring in part and dissenting in part). Five justices therefore concluded that the word

"requirement" in the MDA's express preemption provision was indicative of Congress' intent to preempt common law claims, at least in some circumstances. *Id.* at 2262 (Justices Scalia and Thomas and Chief Justice Rehnquist joined in Justice O'Connor's opinion); *id.* at 2259 ("I basically agree with Justice O'Connor's discussion of this point and with her conclusion.") (Breyer, J. concurring). The remaining four justices disagreed, not on the basis that common law claims do not impose requirements, but because these are not the type of requirements Congress intended the MDA to preempt. *See id.* at 2258 ("These state requirements therefore escape pre-emption, not because the source of the duty is a judge-made common law duty, but rather because their generality leaves them outside the category of requirements § 360k envisioned to be 'with respect to' specific devices such as pacemakers.") (Stevens, J.).

(b) The Court was unanimous in the view that state common law claims would not be preempted to the extent the requirements imposed by such claims were the same as those applicable under the MDA. *Id.* at 2255-2256 (Stevens, J.); *id.* at 2264 (O'Connor, J., concurring in part and dissenting in part). This situation might typically arise in the context of a negligence *per se* claim where state common law incorporates as the appropriate standard of care the same requirements applicable under the MDA. Thus, even though requirements are imposed at both the state and the federal level, there is no preemption because the state-law requirements are identical to, instead of "different from, or in addition to" the relevant federal requirements.

(c) The Court was unanimous in its view that Lohr's design defect claim was not preempted. *Id.* at 2254-55 (Stevens, J.); *id.* at 2263-64 (O'Connor, J., concurring in part and dissenting in part). Without reaching agreement on whether a common law design defect claim could impose a design-related requirement at the state level, all nine justices observed that the regulations governing "substantially equivalent" devices did not impose design-related requirements at the federal level. Absent a federal design requirement, there was nothing for Lohr's state law claims to be "different from, or in addition to," and thus no basis for preemption.

(d) With respect to Lohr's manufacturing and failure to warn claims, all nine justices apparently agreed that the device at issue was subject to federal requirements imposed under the MDA. *See id.* at 2258 (acknowledging the existence of federal labeling and manufacturing requirements applicable to medical devices generally); *id.* at 2261 (Breyer, J., concurring in part and concurring in the judgment); *id.* at 2264 (O'Connor, J., concurring in part and dissenting in part). Four justices concluded that the existence of federal requirements applicable to the device was sufficient to trigger preemption under the MDA. *Id.* at 2264 ("These extensive federal manufacturing and labeling requirements are certainly applicable to the device manufactured by Medtronic [and] [s]ection 360k(a) requires no more specificity than that for pre-emption of state common-law claims.") (O'Connor, J., concurring in part and dissenting in part). The five justices comprising the plurality disagreed, not on the basis that there were no federal requirements, but because these were not the type of requirements Congress intended to have a preemptive effect. *Id.* at 2258 (MDA was not designed to protect "generic" federal requirements "from potentially contradictory state requirements.") (Stevens, J.); *id.* at 2261 (FDA "does not intend [applicable federal] requirements to pre-empt the state requirements at issue here.") (Breyer, J., concurring in part and concurring in the judgment).

(e) The five justices who believed that the federal requirements applicable to "substantially equivalent" devices were not intended to have a preemptive effect relied heavily on interpretative regulations promulgated by the FDA. *See, e.g., id.* at 2255-58 (discussing FDA's interpretive regulations with approval) (Stevens, J.); *id.* at 2260-61 (same) (Breyer, J., concurring in part and concurring in the judgment). Those regulations state that:

> State . . . requirements are preempted only when . . . there are . . . specific [federal] requirements applicable to a particular device . . . thereby making any existing divergent State . . . requirements applicable to the device different from, or in addition to, the specific [federal] requirements.

Id. at 2260-61 (paraphrasing 21 C.F.R. § 808.1(d)).

The FDA's interpretive view persuaded the *Lohr* plurality that federal requirements imposed under the MDA must be device-specific to preempt state law. The plurality concluded that the "general" requirements applicable to "substantially equivalent" devices under the MDA where not sufficiently specific have preemptive effect. Thus, the narrow holding of *Lohr* is that the MDA preempts state law requirements only where they add to or differ from specific federal requirements applicable to a particular device or class of devices.

(f) In deciding to accord "substantial weight" to the FDA's interpretation of the MDA's preemptive scope, the plurality was guided by its understanding of "the structure and purpose" of the MDA as a whole, and significantly, by implied, rather than express preemption principles. For instance, Justice Stevens explains the plurality's reliance on the FDA's interpretive regulations as follows:

> Because the FDA is the federal agency to which Congress has delegated its authority to implement the provisions of the Act, the agency is uniquely qualified to determine whether a particular form of state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress," *Hines v. Davidowitz*, 312 U.S. 62, 67 (1941), and, therefore, whether it should be preempted.

Id. at 2255 (Stevens, J.).

Of course, the question whether state law "stands as an obstacle to the accomplishment and purpose" of federal law has long been viewed as a question of implied preemption, and *Hines* is among the Court's leading implied preemption decisions. Justice Stevens' subsequent observation that "it is impossible to ignore [the MDA's] overarching concern that pre-emption occur only where a particular state requirement threatens to interfere with a specific federal interest" similarly invokes implied preemption concepts. *See id.* at 2257. Notably,

Justice Stevens' opinion closes with an invitation to undertake an implied preemption analysis in future cases involving questions of preemption under the MDA. *Id.* at 2259.

In his concurring opinion, Justice Breyer likewise introduces implied preemption principles to support his conclusion. Specifically, Justice Breyer discusses "ordinary principles of 'conflict' and 'field' preemption" and states that "[i]t makes sense, in the absence of any indication of a contrary congressional (or agency) intent, to read the [MDA and its related regulations] in light of these basic preemption principles." *Id.* at 2261 (Breyer, J., concurring in part and concurring in the judgment).

Given the remarkable number of references to implied preemption principles in a case involving an express preemption provision, it is perhaps not surprising that Justice Stevens' analysis starts off citing *Gade v. National Solid Wastes Management Ass'n*, 505 U.S. 88 (1992), a decision in which a majority of the Court could not agree whether the federal law at issue impliedly or expressly preempted certain regulations arising under state law. *Lohr*, 115 S. Ct. at 2250, 2251 (citing and quoting *Gade*). In view of the ambiguity which the plurality found in the express preemption language of the MDA, however, and in view of the considerable effort devoted to discussing the purpose and goals of Congress when it enacted the MDA, it is also not surprising that the plurality turned to implied preemption principles to inform, if not to justify, its decision.

Respondents submit that this latter observation holds the key to understanding the *Lohr* Court's decision. While the narrow holding described above adequately explains the result in *Lohr*, a complete understanding of the Court's decision must look to the rationale underlying the plurality's conclusion. *Lohr* teaches that it may sometimes be difficult to apply the "plain language" of a preemption provision in a way that is consistent with the greater goals Congress had in mind when it enacted the federal statute. Accordingly, unless Congress works with absolute precision, courts undertaking a preemption analysis must bear in mind the purpose and goals of the

federal statute at issue and determine, ultimately, whether enforcement of state law would interfere with the fulfillment of that purpose and the accomplishment of those goals.

B. *Martin v. Telectronics*

Far from conflicting with the teaching of *Lohr*, the United States Sixth Circuit Court of Appeals thoughtfully and faithfully worked through the analysis suggested by this Court. The court began by reciting the MDA's express preemption provision, and, after reviewing this Court's *Lohr* decision, undertook an analysis of the purpose and structure of the MDA as it pertains to the investigational device at issue here. *See Martin*, 105 F.3d at 1093-97.

Initially, the court observed that the purpose of the investigational device exemption is "to encourage, to the extent consistent with the protection of public health and safety and with ethical standards, the discovery and development of useful devices intended for human use." *Id.* at 1095. The court then reviewed the "complex and comprehensive regulations" applicable to investigational devices, *id.* at 1095-96, and noted that the FDA must be satisfied that "the risks to the subjects are not outweighed by the anticipated benefits to the subjects and the importance of the knowledge to be gained" before it will grant an exemption for a proposed investigation. *Id.* at 1096.

Having established this background, the court turned to a careful comparison between the claims raised by Petitioners below and the federal regulations governing the investigational device at issue. With respect to Petitioners' manufacturing defect claim, the court first determined that there were federal manufacturing regulations "specific to investigational devices." *Id.* at 1098. Without more, this conclusion would have been enough to trigger preemption under the narrow holding of *Lohr* described above. The court expressed concern, however, because it was "questionable" whether the state statute giving rise to Petitioners' claim was developed "with respect to" the device or was merely one of general applicability and therefore did not impose the type of requirement Congress intended for the MDA to preempt. *Id.* at

1099. Looking to implied preemption principles, however, the court concluded that enforcement of Petitioners' manufacturing defect claim "would thwart the goals of the IDE exemption 'to encourage . . . the discovery and development of useful devices intended for human use." *Id.* Accordingly, the court held the manufacturing defect claim preempted. *Id.*

With respect to Petitioners' design defect claim, the court noted that Ohio law provides for a risk/benefit standard or a consumer expectation standard. *Id.* (quoting Ohio Rev. Code § 2307.75). Recalling that the FDA conducts its own device-specific risk benefit analysis prior to granting any investigational device exemption, the court concluded that Ohio law would impose a different requirement insofar as a jury could conclude that the risks of the investigation outweighed its benefits — in contradiction to the FDA's prior determination — and an additional requirement insofar as Ohio law was allowed to superimpose a consumer expectation test on the risk/benefit test required under the MDA. *Id.* Moreover, the court concluded that the enforcement of either standard would "impede the implementation and enforcement" of the applicable provisions of the MDA. *Id.* For all of these reasons, the court found Petitioners' design defect claim preempted.

Petitioners' inadequate warning claims were likewise preempted because of the specific federal provisions governing warning labels and informed consent forms which must be used in conjunction with IDE devices, and as well because enforcement of the state law claim "would impede Congress' intent in enacting the investigational device exemption." *Id.* at 1100. Petitioners' express representation claim was held preempted on the same grounds. *Id.* at 1100-01. Significantly, the court noted that Petitioners had not claimed that Respondents failed to comply with requirements applicable to the device under the MDA's investigational device provisions. *Id.* at 1101.[1]

As can be seen, the *Martin* court conducted a thorough analysis

1. Petitioners' remaining claims, supplier liability and loss of consortium, presented only minor variations on the more substantive claims discussed above. Accordingly, the court did not devote substantial effort to their analysis. *See id.* at 1101.

to ascertain the intent of Congress' in enacting the investigational device provisions of the MDA, and, on a claim by claim basis, determined whether Petitioners' state law causes of action were consistent with, or stood as an obstacle to the accomplishment of that intent. The *Martin* court's approach, and its reasoning, are entirely consistent with this Court's decision in *Lohr*. That the results are different can be readily explained by the different federal regulations governing the respective devices in the two cases.

As noted previously, the federal regulations governing the "substantially equivalent" device at issue in *Lohr* were intended as a stop-gap measure to maintain the status quo until the FDA could implement the substantive provisions of the MDA. And, as this Court observed, the "substantial equivalence" review process does not carry with it the FDA imprimatur of safety and efficacy. Accordingly, the statutory and regulatory provisions applicable to the device in *Lohr* do little if anything to promote the first stated goal of Congress when it enacted the MDA — enhancing public health and safety.[2]

Similarly, almost by definition, the regulations applicable to the *Lohr* device do nothing to promote the second stated goal of the MDA — encouraging innovation. Obviously, regulations which permit pre-1976 medical devices and their post-1976 substantial equivalents to remain on the market do not foster the development of anything new

2. In 1990, Congress amended the MDA to include more stringent safety and effectiveness requirements for manufacturers of "substantially equivalent" devices. *See* 104 Stat. 4515, 4517, 4523, 4528 (1990); *see also* 21 C.F.R. § 807.87(i) (safety and effectiveness regs for post-1990 substantially equivalent devices). These amendments simply codified what had been the past practice of the FDA for at least some substantially equivalent devices. *See* S. Rep. No. 513, 101st Cong., 2d Sess. 28 (1990). In certain cases, for instance, the FDA requires safety and effectiveness data generated in an IDE investigation prior to permitting even a substantially equivalent device to enter the market. *See* 21 C.F.R. §§ 807.92(b)(2) (referring to data from clinical studies included in a § 510(k) submission). The device at issue in *Lohr* was authorized for distribution in 1982, well in advance of the 1990 amendments. *Lohr*, 116 S. Ct. at 2248. The *Lohr* Court did not discuss and apparently had no reason to believe that the device at issue had been subjected to the higher level of safety and effectiveness review contemplated by the amended statute.

in medical device technology. In fact, the substantial equivalence process may actually discourage innovation: rather than developing new devices which must undergo the closely scrutinized IDE process and the exhaustive PMA process, manufacturers may actually have an incentive to rely on old technology insofar as it allows them to reach the market more quickly through the less stringent substantial equivalence regulations. *See Lohr*, 116 S. Ct. at 2248 ("Medtronic took advantage of § 510(k)'s expedited process in October of 1982 when it notified FDA that it intended to market its Model 4011 pacemaker lead as a device that was 'substantially equivalent' to devices already on the market.").

It is not surprising, then, that the *Lohr* Court did not find the claims at issue in that case to have been preempted by the MDA. As the plurality logically observed, by including the substantial equivalence provisions in the MDA

> Congress intended merely to give manufacturers the freedom to compete, to a limited degree, with and on the same terms as manufacturers of medical devices that existed prior to 1976. There is no suggestion in either the statutory scheme or the legislative history that the [substantial equivalence] exemption process was intended to do anything other than to *maintain the status quo*. That status quo included the possibility that the manufacturer of the device would have to defend itself against state-law claims of negligent design. Given this background behind the "substantial equivalence" exemption, the fact that "[t]he purpose of Congress is the ultimate touchstone in every pre-emption case, and the presumption against pre-emption, the Court of Appeals properly concluded that the "substantial equivalence" provision did not pre-empt the Lohrs' design claims.

Lohr, 116 S. Ct. at 2255 (citations omitted) (emphasis added).

By contrast to the statutes and regulations at issue in *Lohr*, the provisions of the MDA applicable to the investigational device at issue here were clearly intended to promote the twin aims of Congress — safety and innovation — and *to change the status quo* in both regards. As this Court noted, the MDA "certainly reflects" Congressional intent to promote innovation in medical device technology. *Lohr*, 116 S. Ct. at 2253 & n.12. In fact, the investigational device exemption appears to be the exclusive vehicle chosen by Congress to promote this goal.

Moreover, the IDE provisions of the MDA allow limited distribution of new devices for the purpose of clinical evaluation and data gathering necessary to determine whether the device is safe and effective. *See id.*; *see also* 21 C.F.R. § 812.1(a). To the extent these provisions allow the collection of clinical data necessary to the PMA review and approval process, they support Congress' goal of enhancing public health and safety in addition to encouraging innovation. *See, e.g.*, 21 C.F.R. § 814.20(b)(3)(v)(B) (discussing inclusion of IDE clinical data in PMA application). It must also be noted that all of the statutory and regulatory provisions governing IDE devices were specifically designed to balance "the protection of public health and safety" with the need to encourage "the discovery and development of useful devices." 21 U.S.C. § 360j(g)(1); 21 C.F.R. § 812.1(a). Thus, perhaps more so than any other provision of the MDA, the IDE requirements were intended to promote both stated goals of Congress.

The IDE regulations differ from those applicable to "substantially equivalent" devices in other ways as well. Unlike the "general federal requirements" discussed in *Lohr*, the MDA's statutory and regulatory structure reveals that the requirements imposed on manufacturers of investigational devices are truly device-specific. For example, the MDA's PMA requirements are the default for all Class III devices. 21 U.S.C. § 360e(a). The IDE regulations do not come into play unless and until a manufacturer submits an IDE application and an investigational plan for a specific device. 21 U.S.C. § 360j(g)(2) (directing the FDA to promulgate regulations whereby a Class III device "may *upon application* be granted an exemption" from PMA

requirements) (emphasis added); *id.* § 360j(g)(2)(B)(ii) (defining requirements applicable to "the person applying for an exemption for *a device*) (emphasis added). The entire content of the application is particular to that device, *see* 21 C.F.R. § 812.20, as is the proposed investigational plan, *see id.* § 820.25.

FDA review and action on an IDE application is similarly device-specific. *See id.* § 812.30(b). For instance, the FDA requires information regarding "the methods, facilities, and controls used for the manufacture . . . of *the device*, in sufficient detail so that a person generally familiar with good manufacturing practices can make a knowledgeable judgment about the quality control used in the manufacture of *the device*," but exempts the manufacturer from the Good Manufacturing Practice requirements which would otherwise apply. 21 C.F.R. § 812.30(b)(3) (requiring manufacturing process information) (emphasis added); § 812.1(a) (exempting investigational device manufacturers from GMP requirements). Perhaps most significantly, the grant of an investigational device exemption for a particular device comes only through a specific FDA order. *Id.* § 812.30(a)(2). This process of application, review and approval-by-order leaves little room for doubt that the requirements imposed on a particular investigational device under the MDA are specific indeed.

Finally, and of significance to the *Martin* court, the FDA conducts a "risk/benefits" analysis for each investigational device application and grants an exemption only if "the risks to the subjects" are "outweighed by the anticipated benefits to the subjects and the importance of the knowledge to be gained" from the particular investigation under review. *Martin*, 105 F.3d at 1096, 1099; *see also* 21 C.F.R. § 812.30(b)(4); 21 C.F.R. § 56.111 (requiring similar risk/benefit analysis to be undertaken by the Institutional Review Board responsible for overseeing the investigation). This type of FDA oversight is apparently significant to this Court as well; discussing the federal regulations applicable to the "substantially equivalent" device in *Lohr*, the Court observed that:

> The generality of [the substantial equivalence]

> requirements make this quite unlike a case in which the Federal Government *has weighed the competing interests* relevant to the particular requirement in question, reached an unambiguous conclusion about how those competing considerations should be resolved *in a particular case or set of cases*, and implemented that conclusion via *a specific mandate on manufacturers* or producers.

Lohr, 116 S. Ct. at 2258 (emphasis added).

In view of the foregoing, Respondents submit that the Sixth Circuit Court of Appeals has faithfully adhered to this Court's teaching in *Lohr*. Further, Respondents submit that the reasoning of *Lohr*, when applied to the particular facts and the particular state and federal laws at issue in this case, supports the different result reached by the Sixth Circuit. There is no conflict and no inconsistency in the application of law, and the decision of the Sixth Circuit should stand.

C. Conflict with Other Decisions

Petitioners also suggest that the Sixth Circuit's decision conflicts with decisions from other federal appellate courts. A brief discussion of each of the cases cited by Petitioners reveals the fallacy of this argument.

1. *Oja v. Howmedica*

This Tenth Circuit decision is easily distinguishable on several grounds. First, the device at issue — a prosthetic hip replacement — was being marketed under § 510(k) of the MDA at the time of plaintiff's implant surgery. *Oja v. Howmedica, Inc.*, 111 F.3d 782, 1997 U.S. App. LEXIS 7175 (10th Cir. 1997). At least that was true for the version of the product used with bone cement. *Id.*, 1997 U.S. App. LEXIS at *10. At some point, Howmedica submitted an IDE application to conduct a clinical study of the device without bone cement. *Id.* This application was still pending, however, when the plaintiff's physician

decided to implant the device without using cement. *Id.* at *10 & n.2. Thus, it is unclear whether *any* federal requirements were applicable to the device at issue. Ultimately, the FDA classified the device — used with or without bone cement — as Class II. *Id.* at *11-12. Without ever stating precisely what federal requirements may have been applicable to the device, the Tenth Circuit noted that the device was not subject to IDE regulations, and thus distinguishable from the device at issue in *Martin* and in *Becker v. Richards Medical Co.*, 937 F. Supp. 181 (N.D.N.Y. 1996). *See id.* at *10 n. 2.

2. *Duvall v. Bristol-Myers-Squibb Co.*

Like *Lohr*, but unlike the instant case, *Duvall* involved a "substantially equivalent" device authorized for market distribution pursuant to § 510(k) of the MDA. *Duvall v. Bristol-Myers-Squibb Co.*, 103 F.3d 324, 328 (4th Cir. 1996). Petitioners point out that prior to achieving "substantially equivalent" status, the device had undergone clinical testing pursuant to an investigational device exemption. The Fourth Circuit's opinion is unequivocal, however, in its treatment of the device as "substantially equivalent" rather than investigational. *Id.* at 328. There is no suggestion in the court's opinion that the plaintiff took part in the investigation or was otherwise afforded the protections, such as the requisite informed consent, typically associated with investigational devices.

3. *Chambers v. Osteonics Corp.*

Petitioners partially mischaracterize this decision as one in which a "negligent manufacturing claim" against the manufacturer of an investigational hip prosthesis was not preempted. In fact, the Seventh Circuit held that all of the plaintiff's claims *except* negligent manufacturing were preempted by the MDA. *Chambers v. Osteonics Corp.*, 109 F.3d 1243, 1997 U.S. App. LEXIS 6301 (7th Cir. 1997). Moreover, the single claim that survived preemption did so only because the plaintiff's claim was "expressly limited to Osteonics' failure to comply with the standards and procedures set out by the FDA in the IDE process." *Id.*, 1997 U.S. App. LEXIS 6301 at *16. The Sixth

Circuit in *Martin* explicitly agreed with this position, noting that "a claim that [Respondents] did not comply with MDA regulations governing its device would not be preempted. . . ." *Martin*, 105 F.3d at 1101. Unfortunately for Petitioners, the Sixth Circuit also noted that Petitioners "failed to allege below that [Respondents] did not comply with MDA regulations governing devices approved under the IDE. Thus, any remedy available to [Petitioners] under a failure to comply with federal regulations theory has been waived." *Id.*

4. *Papike v. Tambrands, Inc.*

As Petitioners concede, this case involves a Class II rather than a Class III device, and has nothing whatever to do with the regulations governing investigational device exemptions. *Papike v. Tambrands, Inc.*, 107 F.3d 737, 1997 U.S. App. LEXIS 2870 (9th Cir. 1997). The decision thus has little if any bearing on the question of preemption in the context of a Class III investigational device such as the one at issue here. Perhaps the most significant aspect of *Papike* lies in its acknowledgment that the conclusions drawn by the same court in *Kennedy v. Collagen Corp.*, 67 F.3d 1453 (9th Cir. 1995) — that common law claims against the manufacturer of a Class III PMA device were not preempted — "cannot survive in light of the concurring and dissenting opinions" in this Court's *Lohr* decision. *Papike*, 1997 U.S. App. LEXIS at *11-12.

5. *Reeves v. Acromed Corp.*

This case involves a "substantially equivalent" device and, not surprisingly, replicates the reasoning and result of *Lohr*. *See Reeves v. Acromed Corp.*, 103 F.3d 442 (5th Cir. 1997). As such, it adds little to the discussion of preemption under the MDA with respect to investigational devices.

6. *Wilson v. Bradlees of New England, Inc.*

Petitioners' reference to this decision is somewhat bewildering in that it involves children's clothing rather than medical devices, and involves a completely different federal statute with an express

preemption provision that speaks of "standard[s]" and "regulation[s]" rather than the more general "any requirement" language in the MDA. *See Wilson v. Bradlees of New England, Inc.*, 96 F.3d 522 (1st Cir. 1996). As noted in Section III of this brief, however, Petitioners' citation to *Wilson* as a plea for additional guidance on the question of federal preemption may be one worthy of this Court's consideration.

II. THIS CASE DOES NOT PRESENT A CONSTITUTIONAL ISSUE THAT SHOULD BE DECIDED BY THIS COURT [RESTATED].

The Constitution establishes our federal government as a government of limited powers, and carefully defines the areas in which federal authority may appropriately be exercised. Within those carefully defined areas, however, the "Supremacy Clause" of the Constitution provides that federal law "shall be the supreme Law of the Land . . . , any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const., art. VI, cl. 2. This Court has held again and again that Congress has the authority under the Supremacy Clause to preempt state law, including state common law claims. *E.g., American Airlines, Inc. v. Wolens*, 115 S. Ct. 817 (1995); *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992); *Morales v. Trans World Airlines, Inc.*, 504 U.S. 374 (1992); *Chicago & N.W. Transportation Co. v. Kalo Brick & Tile Co.*, 450 U.S. 311 (1981); *Texas & Pacific Rwy. Co. v. Abilene Cotton Oil Co.*, 204 U.S. 426 (1907).

Notwithstanding this precedent, Petitioners submit that the Seventh Amendment constrains the supremacy of federal law to the extent it impacts upon any state common law claims that existed as of December 15, 1791, the date the Seventh Amendment was ratified. In other words, Petitioners assert that Congress is powerless to preempt traditional state common law claims even when Congress is appropriately exercising the authority given it under Article I of the Constitution.[3]

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3. Petitioners have not suggested that federal regulation of medical devices, as embodied in the Medical Device Amendments to the Food, Drug and Cosmetic Act, is an inappropriate exercise of Congressional power or that such regulation exceeds the limits established in Article I.

This argument misapprehends the language, the scope and the very purpose of the Seventh Amendment and thus does not raise a Constitutional issue worthy of review by this Court.

In its entirety, the Seventh Amendment provides:

> In Suits at common law, where the value in controversy shall exceed twenty dollars, the right of trial by jury shall be preserved, and no fact tried by a jury, shall be otherwise reexamined in any Court of the United States, than according to the rules of common law.

As the language of the amendment itself makes plain, the right being protected — the right to a jury trial in civil lawsuits —presupposes the existence of a "Suit[] at common law." In this case, there is no "Suit[] at common law" because Petitioners' common law claims have been expressly preempted, a priori, by the Medical Device Amendments to the federal Food, Drug and Cosmetic Act. Where there is no "Suit[] at common law" due to the operation of the Supremacy Clause, the right of trial by jury simply is not implicated because there is no underlying lawsuit to which the right can attach.

The Sixth Circuit Court of Appeals correctly stated this principle, observing that

> [n]othing in its text or history indicates that the Seventh Amendment protects the existence of certain common-law causes of action. . . . Here, as plaintiffs' causes of action have been preempted by federal law, they have no "suit[] at common law" and the Seventh Amendment's guarantees are not implicated.

Martin v. Telectronics Pacing Systems, Inc., 70 F.3d 39, 42 (6th Cir. 1995). The court reiterated this view on remand, stating that "We see

no reason to depart from our previous holding on this issue." *Martin*, 105 F.3d 1090, 1101 (6th Cir. 1997). This same reasoning is reflected in numerous court decisions holding that there is no constitutionally protected right to bring a tort claim.[4] The reasoning articulated by the Sixth Circuit Court of Appeals also comports with numerous analogous decisions involving the right of trial by jury. For example, in *Etalook v. Exxon Pipeline Co.*, 831 F.2d 1440 (9th Cir. 1987), the court addressed the question whether granting summary judgment infringes on a litigant's right to a jury trial. The court concluded that "no right of jury trial exists unless there is a genuine issue of material fact suitable for a jury to resolve." *Id.* at 1447. Similarly, in *3 Penny Theater Corp. v. Plitt Theatres, Inc.*, 812 F.2d 337 (7th Cir. 1987), the court concluded that dismissal of a plaintiff's claims with prejudice for failure to prosecute pursuant to Fed. R. Civ. P. 41(b) did not violate the plaintiff's right to a trial by jury. And in *Sullivan v. United States*, 788 F.2d 813 (1st Cir. 1986), the court found no violation of the plaintiff's right to a jury trial based on the trial court's dismissal for failure to state a claim upon which relief could be granted.

In each of the above-cited decisions, the right to trial by jury never arose because plaintiff's claims were determined to be unsupportable *as a matter of law*. Given the time-honored role of juries as finders of *fact*, there is no legal or logical reason for jury involvement in a case that can be and is decided on purely legal grounds. It necessarily follows that claims which can be resolved as a matter of law simply do not implicate the Seventh Amendment guarantees. This case is no different. Petitioners' claims were held to be preempted by the express preemption provisions of the MDA as a matter of law. As a result, the right to trial by jury never becomes an issue.

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4. *See, e.g., Cooperativa de Ahorro y Credito Aguada v. Kidder, Peabody & Co.*, 993 F.2d 269 (1st Cir. 1993) (no protectable right in a tort claim "until a final, unreviewable judgment has been obtained") (citations omitted); *Hammond v. United States*, 786 F.2d 8 (1st Cir. 1988) (same); *Donaldson v. Volkswagenswerk Aktiengesellschaft*, 631 F. Supp. 1144 (S.D. Fla. 1986) (no constitutionally protected right in a tort claim), *aff'd sub nom.*, 835 F.2d 1369 (11th Cir.), *cert. denied sub nom.*, 488 U.S. 822 (1988).

Petitioners' argument to the contrary turns this straightforward calculus on its head. According to Petitioners, it is not the right to jury trial that is preserved by the Seventh Amendment, but the underlying common law claim itself: "Congress cannot pass a law that abrogates an individual's right to a trial by jury where the cause of action existed prior to 1791; and the Seventh Amendment as an amendment takes precedence over the Supremacy Clause." Stretched to its extreme, this argument would make it impossible for a court to ever dispose of a lawsuit on purely legal grounds without running afoul of the Seventh Amendment. Similarly, this argument would make it impossible for Congress to exercise its power under Article I and the Supremacy Clause if, in so doing, it undermined any common law theory of recovery which may have existed in the late eighteenth century.

Indeed, careful consideration of Petitioners' argument reveals inherent contradictions and fatal flaws in logic. For instance, acceptance of Petitioners' argument would, at some fundamental level, result in the wholesale destruction of the common law paradigm. Instead of an evolving body of law representing the culmination of legal principles and societal wisdom gleaned through the ages, Petitioners' vision of the common law is one that is fixed in time. According to Petitioners, the Seventh Amendment essentially codified the common law as it existed in 1791 and admits of no alterations to that codification. Accepting Petitioners' argument would be tantamount to accepting blanket prohibition of the growth, change and adaptation that are the hallmarks of our common law system, and would effectively consign the contributions of such legal lights as Holmes, Cardozo and Llewellyn to the scrap heap. It is doubtful at best whether the Framers could have intended such a result while simultaneously embracing the common law heritage of their English forebears.

That this Court has traditionally taken an "historical approach" in its Seventh Amendment jurisprudence does not save Petitioners' argument. This Court has long interpreted the Seventh Amendment as reaching only those cases cognizable in law, as opposed to those historically brought in equity or admiralty. *See Granfinanciera, S.A. v. Nordberg*, 492 U.S. 33 (1989). To make these distinctions in a manner

consistent with the Framers' intent, this Court has found it is necessary to conduct an historical analysis of the differences among law, equity and admiralty as they existed in 1791. *E.g., Tull v. United States,* 481 U.S. 412 (1987). It is a leap of illogic, however, for Petitioners to draw from this analytical approach the conclusion that the Framers intended the Seventh Amendment to petrify the common law itself as it existed in eighteenth century America.

Petitioners candidly admit there is no authority whatsoever for the proposition that "the Seventh Amendment preserve[s] a cause of action in and of itself." Pet. at 11. Perhaps as a result of this dearth of supporting authority, Petitioners attempt to supplement their Seventh Amendment argument with reference to the Ninth and Tenth Amendments, apparently for the proposition that the Constitution does not grant Congress the authority to preempt state common law claims. No reference was made to the Ninth and Tenth Amendments at trial as potential grounds for invalidating the MDA. Accordingly, these arguments should not now be considered for the first time on appeal.

III. RESPONDENTS ACKNOWLEDGE POTENTIAL CONFLICT BETWEEN THE SIXTH CIRCUIT'S DECISION AND THE DECISION OF THE MISSOURI SUPREME COURT IN *CONNELLY V. IOLAB*, AND RESPECTFULLY SUBMIT THAT THIS CASE PROVIDES THE MORE APPROPRIATE VEHICLE FOR ANY CLARIFICATION BY THIS COURT OF ITS PRIOR DECISION REGARDING THE SCOPE OF PREEMPTION UNDER THE MDA.

Somewhat surprisingly, Petitioners failed to mention the Missouri Supreme Court's decision in *Connelly v. Iolab Corp.*, 927 S.W. 2d 848 (Mo. 1996), *pet'n for cert. pending sub nom., Iolab Corp. v. Hunter*, Docket No. 96-1126, which arguably is one case that does conflict with the Sixth Circuit's *Martin* opinion.

Like this case, *Iolab* involves state law claims against the manufacturer of an investigational device. *Iolab*, 927 S.W. 2d at 850. And like the Sixth Circuit in this case, the Missouri Supreme Court

incorporated implied preemption principles into its analysis. *See id.* at 853-855. There the similarities end. The Missouri court limited its view of preemption under the MDA to those situations where it was impossible to comply with both state and federal law. *Id.* at 853 ("If any basis of common law liability asserted by plaintiffs conflicts with a federal regulation in such a way as to make performance of both impossible, the state common law claim is preempted."). Having adopted this restrictive view, and finding that it was not impossible for the manufacturer to satisfy both the federal IDE requirements and such design, manufacturing, labeling and warning requirements as might be imposed under Missouri common law, the court concluded that none of the plaintiff's claims were preempted.

Iolab petitioned this Court for certiorari review of the Missouri court's decision. Recently, on April 21, 1997, this Court issued an order inviting the Solicitor General to submit a brief on behalf of the United States — and more particularly, the FDA — setting forth the FDA's position on MDA preemption with respect to investigational devices. *Iolab Corp. v. Hunter*, 117 S. Ct. 1466 (1997). As a result of this order, and in view of the persistent confusion among the courts regarding the scope of preemption under the MDA, Respondents believe the Court may be inclined to take up the issue once again, this time in the context of investigational devices.

Should the Court be so inclined, Respondents respectfully submit that the instant case, rather than the *Iolab* case, provides the best opportunity for this Court to explicate its prior decision. In support of this contention, Respondents offer the following observations:

(a) *Martin* potentially reaches a broader range of medical devices, and accordingly a broader range of claims which may be subject to preemption under the MDA. Specifically, the federal regulations at issue in *Martin* pertain to all investigational devices, whereas intraocular lenses, such as the device at issue in *Iolab*, are governed by their own separate set of regulations. *Compare* 21 C.F.R. Part 812 (regulations governing investigational devices generally) *with* 21 C.F.R. Part 813 (regulations governing investigational intraocular lenses). In the event

the Court were to conclude, for instance, that the claims in *Iolab* should be preempted because the federal regulations in question are sufficiently specific, it would remain uncertain whether claims against manufacturers of all other investigational devices are similarly preempted. Moreover, Respondents submit that the Sixth Circuit's careful analysis of the goals underlying the MDA might provide an appropriate platform for guidance on the question of preemption in the context of PMA devices as well. No such opportunity is afforded by the Missouri court's opinion which, quite simply, does not discuss the effect that its decision, and the enforcement of state common law claims, will have on "the accomplishment and execution of the full purposes and objectives of Congress" when it enacted the MDA.

(b) *Martin* provides this Court with an opportunity to put the "common law vs. positive enactments" debate to rest. Specifically, *Martin* involved claims arising under Ohio statutory law because Ohio, like several other states, has chosen to codify its product liability common law. *Martin*, 105 F.3d at 1092; *cf. Chambers v. Osteonics Corp.*, 109 F.3d 1243, 1997 U.S. App. LEXIS 6301 at *16 (7th Cir. 1997) (distinguishing *Martin* on the ground that the claims at issue there arose from Ohio statutory law rather than common law). The nature and the impact of the claims in *Martin* are virtually the same as analogous claims arising under the common law of other jurisdictions. However, the fact that they are premised on "positive enactments of state law" rather than common law will allow this Court to focus narrowly on the type of state-law requirements that should be preempted, regardless of their source.

(c) Although it should not be necessary to the Court's determination, Petitioners' argument regarding the 510(k) status of two component parts of the investigational device in *Martin* raises a recurring question that should be resolved. As noted in both the *Oja* and *Duvall* decisions, different medical devices over the course of their product life cycle may be governed at different times by "substantially equivalent" regulations, IDE regulations, or PMA regulations. This is simply a reality inherent in the structure and the practical application of the MDA. Insofar as this regulatory evolution presents problems for

courts and litigants faced with preemption questions arising under the MDA, *Martin* gives this Court an opportunity to resolve them.

(d) Finally, Respondents submit that the Sixth Circuit's *Martin* decision is the better reasoned and thus provides the better "template" for a clarification decision from this Court. As noted previously, the Sixth Circuit faithfully adhered to the principles set forth in *Lohr*, beginning with the language of the statute, followed by a reasoned assessment of the structure and purpose of the statute, and turning to fundamental principles of conflict preemption to resolve questions left unanswered by the MDA's express preemption language. By contrast, the Missouri court erroneously described the device at issue in *Lohr* as a hearing aid, *see Iolab*, 927 S.W. 2d at 852, treated as a holding the "common law vs. positive enactment" distinction which did not command a majority of the Court, *see id.* at 853 ("Under the plurality opinion, there are no positive enactments of state statutes or regulations at issue here and thus no preemption."), and, without explanation or justification, limited the application of implied preemption principles to situations in which compliance with both state and federal requirements was "impossible." *See id.*

For all the foregoing reasons, Respondents respectfully suggest that the Court give favorable consideration to this case, rather than the *Iolab* case, in the event it is inclined to revisit the question of preemption under the MDA in the context of investigational devices.

CONCLUSION

For the foregoing reasons, Respondents pray that this Court deny the Petition for Writ of Certiorari sought by Petitioners, thus maintaining intact the considered opinion of the Sixth Circuit Court of Appeals. However, should this Court be inclined to revisit the question of federal preemption under the MDA in the context of investigational devices, Respondents respectfully submit that it would be preferable for the Court to review the Sixth Circuit's decision in *Martin* rather than the decision of the Missouri Supreme Court in *Connelly v. Iolab.*

Respectfully submitted,

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